

## PATENT COOPERATION TREATY

PCT

From the INTERNATIONAL BUREAU

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

To:

HOWARD, Paul, Nicholas  
Carpmaels & Ransford  
43 Bloomsbury Square  
London WC1A 2RA  
ROYAUME-UNI

Date of mailing (day/month/year) 13 July 2000 (13.07.00)	<b>IMPORTANT NOTIFICATION</b>
Applicant's or agent's file reference KVC/P21509WO	
International application No. PCT/GB00/00086	International filing date (day/month/year) 13 January 2000 (13.01.00)

1. The following indications appeared on record concerning:	
<input type="checkbox"/> the applicant	<input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative
Name and Address CORNISH, K., V., J. Kilburn & Strode 20 Red Lion Street London WC1R 4PJ United Kingdom	State of Nationality
	State of Residence
	Telephone No. 0171 539 4200
	Facsimile No. 0171 539 4299
Teleprinter No.	
2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:	
<input checked="" type="checkbox"/> the person <input type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence	
Name and Address HOWARD, Paul, Nicholas Carpmaels & Ransford 43 Bloomsbury Square London WC1A 2RA United Kingdom	State of Nationality
	State of Residence
	Telephone No. 020 7242 8692
	Facsimile No. 020 7405 4166
Teleprinter No.	
3. Further observations, if necessary:	
4. A copy of this notification has been sent to:	
<input checked="" type="checkbox"/> the receiving Office	<input checked="" type="checkbox"/> the designated Offices concerned
<input type="checkbox"/> the International Searching Authority	<input type="checkbox"/> the elected Offices concerned
<input type="checkbox"/> the International Preliminary Examining Authority	<input type="checkbox"/> other:

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer R. Chrem
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PCT COOPERATION TREATY

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## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 14 September 2000 (14.09.00)	<b>Applicant's or agent's file reference</b> KVC/P21509WO
<b>International application No.</b> PCT/GB00/00086	<b>Priority date (day/month/year)</b> 13 January 1999 (13.01.99)
<b>International filing date (day/month/year)</b> 13 January 2000 (13.01.00)	
<b>Applicant</b> CAMPBELL, Keith, H., S.	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

09 August 2000 (09.08.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b>  Juan Cruz
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>KUC/P21509W0</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/GB 00/ 00086</b>	International filing date (day/month/year) <b>13/01/2000</b>	(Earliest) Priority Date (day/month/year) <b>13/01/1999</b>
Applicant <b>PPL THERAPEUTICS (SCOTLAND) LIMITED et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the international Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1  
☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International Application No

PT/GB 00/00086

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12N15/00 A01K67/027 A61K48/00 C12N5/10 C12N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A01K C07K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 39416 A (STRELCHENKO NIKOLAI S ;INFIGEN INC (US); PACE MARVIN M (US); JURGE) 11 September 1998 (1998-09-11) page 5, line 15 - line 19 page 59, line 23 -page 61, line 14; example 5 page 9, line 13 - line 23 page 11, line 12 - line 23 page 12, line 2 - line 3 page 35, line 11 - line 17; figures 2-4 ---	1,37-41
X	WO 98 57538 A (PRATHER RANDALL S ;UNIV MISSOURI (US); MACHATY ZOLTAN (US)) 23 December 1998 (1998-12-23) claim 17 --- -/--	1,37-41

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 June 2000

Date of mailing of the international search report

19/06/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Chambonnet, F

# INTERNATIONAL SEARCH REPORT

International Application No

/GB 00/00086

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 97 07668 A (CAMPBELL KEITH HENRY STOCKMAN ; ROSLIN INST EDINBURGH (GB); WILMUT) 6 March 1997 (1997-03-06) cited in the application	1
X	the whole document ---	37-41
A	WO 97 07669 A (CAMPBELL KEITH HENRY STOCKMAN ; ROSLIN INST EDINBURGH (GB); WILMUT) 6 March 1997 (1997-03-06) cited in the application	1
X	the whole document -----	37-41

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

T/GB 00/00086

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9839416	A	11-09-1998	AU 6688098 A EP 0973871 A US 6011197 A	22-09-1998 26-01-2000 04-01-2000
WO 9857538	A	23-12-1998	AU 7979098 A	04-01-1999
WO 9707668	A	06-03-1997	AU 6830996 A BR 9610013 A CA 2229657 A CN 1202085 A CZ 9800604 A EP 0847237 A GB 2318792 A GB 2340493 A HU 9802485 A NO 980846 A PL 325336 A	19-03-1997 21-12-1999 06-03-1997 16-12-1998 15-07-1998 17-06-1998 06-05-1998 23-02-2000 01-02-1999 29-04-1998 20-07-1998
WO 9707669	A	06-03-1997	AU 716956 B AU 6831096 A BR 9610034 A CA 2229568 A CN 1202084 A CZ 9800608 A EP 0849990 A EP 0930009 A EP 1005789 A GB 2318578 A,B GB 2331751 A,B HU 9900234 A NO 980845 A NZ 316149 A PL 325331 A	09-03-2000 19-03-1997 21-12-1999 06-03-1997 16-12-1998 15-07-1998 01-07-1998 21-07-1999 07-06-2000 29-04-1998 02-06-1999 28-05-1999 29-04-1998 28-10-1999 20-07-1998

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

9/600130 14.  
REC'D 27 MAR 2001

Applicant's or agent's file reference P024864WO:PNH	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/00086	International filing date (day/month/year) 13/01/2000	Priority date (day/month/year) 13/01/1999
International Patent Classification (IPC) or national classification and IPC C12N15/00		
Applicant PPL THERAPEUTICS (SCOTLAND) LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  09/08/2000	Date of completion of this report  23.03.2001
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Giebeler, K  Telephone No. +49 89 2399 8546  

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00086

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-52 as originally filed

### Claims, No.:

1-41 as originally filed

### Drawings, sheets:

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00086

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Yes:	Claims	1-35
	No:	Claims	36-41
Inventive step (IS)	Yes:	Claims	1-35
	No:	Claims	36-41
Industrial applicability (IA)	Yes:	Claims	36-41
	No:	Claims	1-35

2. Citations and explanations  
**see separate sheet**

## VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

**R Item V**

**Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. The following documents are cited:  
D1: WO 98 39416 A  
D2: WO 98 57538 A  
D3: WO 97 07668 A  
D4: WO 97 07669 A
2. The present application does not satisfy the criterion set forth in Article 33(1)(2) PCT because the subject-matter of claims 36-41 is not new. These claims 36-41 define products in terms of processes for their preparation and lack novelty over each of the documents D1, D2, D3 and D4. A product is not rendered novel merely by the fact that it is produced by a novel process.
3. The methods of claims 1-35 are considered to be both novel and inventive over the available prior art. D1 appears to represent the closest prior art document. The method of claim 1 requires that a nucleus is transferred into an oocyte and removed **before** mitotic cell division occurs, whereas in D1, the recipient of the first nuclear transfer step is allowed to develop into a multi-cell embryo (see especially step (c) in Figure 2 of D1). The technical problem to be solved is seen in the provision of further methods of cloning animals. The post-published evidence submitted by the Applicant shows that this problem has actually been solved. Since it does not appear to be derivable from any of the available prior art documents to perform the second nuclear transfer step at an early stage, an inventive step can be acknowledged.
4. For the assessment of the present claims 1-35 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

**Re Item VIII****Certain observations on the international application**

5. Claims 36-41 define products in terms of processes for their preparation, which is only considered to be clear if there is no other information available in the application which could enable the applicant to define the product satisfactorily by reference to its composition, structure or other testable parameters.
6. The claims include human cloning methods and human embryos in their scope. Therefore, the present IPEA considers the claimed invention to be contrary to morality.